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Evaluation of intervention strategies to manage fatigue during active treatment and to prevent persistent fatigue after curative treatment for cancer

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Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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KUN 2005-3206; NTR183

Study information

Scientific Title

Study objectives
Fatigue is a nearly universal symptom in patients receiving cancer treatment. Up to 99% of all cancer patients have to deal with some degree of fatigue during treatment. Based on the literature and our own experience it can be concluded that one year after successful cancer treatment severe fatigue persists in at least 40% of the survivors. Looking at heightened fatigue we found even a percentage of 60%. Cancer patients as well as cancer survivors who experience severe fatigue can not participate fully anymore in the roles and activities that make life meaningful. Little research has been done in this domain and the exact mechanisms involved are still unknown. Controlled studies concerning the elements for combating fatigue during active treatment are lacking. Nevertheless, activity enhancement and psychosocial interventions have the strongest evidence as a base for managing fatigue during active cancer treatment.

At this moment the Expert Centre Chronic Fatigue is conducting an intervention study to reduce fatigue and functional impairment in cancer survivors. Preliminary data of this study show positive effects. Preventing fatigue in cancer survivors by an intervention in an earlier stage would be more desirable. Therefore the purpose of this study is to evaluate whether an intervention (a minimal or a more intensive one) during treatment of cancer is effective in managing fatigue during cancer treatment and whether these interventions can prevent fatigue becoming persistent, one year after the curative treatment has ended.

Furthermore, this study will also look at the early determinants of persistent fatigue after curative treatment for cancer, so it will provide us a more complete understanding of the course of fatigue from the start of the treatment.

Hypotheses:
1. What are the effects of a minimal intervention given by a nurse and a more intensive psychological intervention on managing fatigue during active treatment of cancer compared to no intervention? Will a minimal intervention be sufficient or is a more intensive treatment necessary in managing fatigue during active treatment of cancer?
2. What are the effects of a minimal and a more intensive psychological intervention during active treatment of cancer on persistent fatigue in disease-free cancer patients one year after completion of treatment of cancer?
3. Which factors, somatic and/or psychological, during treatment of cancer have predictive value for persistent fatigue in disease-free cancer patients one year after completion of treatment of cancer?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local ethics committee (Commissie Mensgebonden Onderzoek Regio Arnhem - Nijmegen) on the 16th June 2005 (ref: CMO-nr.: 2005/082).

Study design
Randomised, active controlled, parallel group, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer, curative treatment, fatigue

Interventions
Intervention 1: minimal intervention:
The minimal intervention consists of a booklet with easily understood general information about two components. In two one hour sessions the research nurse will explain the booklet and help the patient to apply this to their situation. General information about fatigue during active treatment will be given.

The second component consists of physical activity instructions. In the second session also the adherence of the patients to the instructions will be discussed.

Intervention 2: cognitive behavioural therapy (CBT):
The patients randomised to the CBT condition will also get and discuss the booklet given in the minimal intervention condition. Additionally, they will get individual treatment that consists of ten sessions with a psychotherapist of the Expert Centre Chronic Fatigue in about six months. In the treatment program seven phases can be discerned. The importance of each phase depends on the relevance for the individual patient, which is determined by multidimensional individual assessment:

Phase one: learning to cope with emotions evoked by having a life-threatening disease and for which the patient undergoes an intensive treatment.
Phase two: non-helping cognitions around the disease, its treatment and to perform a physical activity program will be disputed. More helping cognitions will be installed in order to start and maintain the activity program.
Phase three: the patients will be taught how to get a more regular sleep/wake cycle, adaptation to the new cancer treatment situation, to look at their sleep pattern and normalise them. This implies going to bed and getting up at fixed times. When sleeping disturbances are present, new sleeping habits as well as alternating rest and activity will be learned.
Phase four: a physical activity program in which patients learn to regulate activities according to ones limit. Patients will be asked to select a physical activity that they can perform every day. Systematic increase of physical and, if necessary, mental activities will take place. Also in this condition the activities are left under control of the patient to permit individualised adaptation

to effects of the cancer treatment and age. Patients have to find the right balance between periods of rest and periods of activity.
Phase five: support of others, emotionally or instrumentally, will be regulated. A relevant person of the patient will be included in the therapy process.
Phase six: stimulation of activities that improve mental functioning. This means engaging in activities that give mental rest and relief. This can help the patient to distract from thoughts of worrying, concerns, pain and stimulate positive thoughts. Distraction can be found in activities that are based on the interest of a patients, like creative activities, activities of fascination, activities that give a sense of being away.
Phase seven: integrating the learned way of thinking and behaving in daily life, in agreement with the individual aims. Which means a return of regularity in daily activities.

During all phases, use of simple diaries with various instructions will help patients to increase self management and self control.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Fatigue severity will be measured using the Checklist Individual Strength. The Checklist Individual Strength is a 20-item questionnaire, designed to measure four aspects of fatigue over the last 14 days, namely:
1. Fatigue severity (eight items)
2. Concentration (five items)
3. Motivation (four items)
4. Physical activity (three items)

Each item is scored on a seven-point Likert scale. High scores indicate a high level of fatigue, a high level of concentration problems, low motivation and a low level of activity. Psychometric properties are excellent. A score of 35 or higher on the subscale fatigue severity indicates severe feelings of fatigue. Norm scores of different patients groups and healthy controls are available.

Secondary outcome measures
1. Psychological distress will be measured by the Symptom Checklist-90 (SCL-90). This 90-item questionnaire consists of the subscales anxiety, agoraphobia, depression, somatisation, obsessive-compulsive behaviour, interpersonal sensitivity, hostility and sleep disturbances
2. Daily observed fatigue will be measured during a two-week period with the Self-Observation List (SOL). This is another important assessment instrument that is developed by our research group. The SOL has been constructed in order to obtain information about severity and frequency of fatigue and other complaints during a two-week period. Fatigue severity is reported four times a day on a four-point scale (zero to 16)
3. During this two-week period physical activity will be measured with the actometer. The actometer is the size of a match box and records the number of movements every five minute period. This apparatus has to be worn around the ankle day and night for a consecutive two-weeks. The actometer has been used satisfactory in several previous studies. In addition, patients report their level of activity four times a day in the Self-Observation List.
4. Physical fitness will be measured by a steptest. The patients will be asked to walk up and down a flight of nine standard stairs at a reasonable but not fixed pace, for one minute. The

resting pulse rate will be measured and the pulse rate 30 seconds after completion of the exercise. A measure of physical fitness will be calculated by dividing the number of stairs climbed by the exercise pulse-rate difference.
5. The Beck Depression Inventory for primary care (BDI-pc) will be used to measure depression. The primary care version will be used to prevent an overlap between the physical aspects of fatigue with the somatic symptoms of depression. This shortened version of the BDI has seven items and is composed of cognitive and affective symptoms only. A score of four or more is indicative of clinical depression.
6. Self-efficacy will be measured using a five-item Self Efficacy Scale, measuring sense of control in relation to fatigue complaints and a general self-efficacy questionnaire. A higher score reflects a higher sense of control.
7. Social Support will be measured with the Social Support Questionnaire. This social support measurement is divided into the SSLI (amount of social interactions) and the SSLD (discrepancies between amount of social support and desired amount of social support). Both the SSLI and SSLD consist of the following subscales:
7.1. Emotional interaction
7.2. Appreciation support
7.3. Emotional support
7.4. Informative support
7.5. Instrumental interaction
7.6. Social companionship, and
7.7. A total score
The SSLI has one extra subscale, which measures negative interactions
8. The European Organisation for Research and Treatment of Cancer will be used to measure the more general concept of quality of life. The EORTC QLQ-C30 (+3) consists of five functional scales (physical-, role-, cognitive-, emotional,- and social functioning), nine symptom scales and one scale for global health status

Overall study start date
01/11/2005

Completion date
01/12/2008

Eligibility

Key inclusion criteria
1. Patients just have been diagnosed for breast cancer, colorectal cancer, cervix cancer, uterus cancer, testis cancer, Hodgkin and non-Hodgkin disease
2. Patients in preparation of receiving therapy with curative intention (chemotherapy, radiotherapy and/or surgery)
3. 18 to 70 years old
4. Patients must be able to speak and write Dutch and to fill out the questionnaires independently
5. Patients have no somatic co-morbidity unrelated to the malignancy, that can co-exist with fatigue

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/11/2005

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center St. Radboud
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Charity

Funder Name
Dutch Cancer Society (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration